

August 12, 2004

Sharon M. Davis
Consumer Safety Officer
Inspection and Compliance Branch
FDA/DCRH/OCER/DMQRP
1350 Piccard Drive (HFZ – 240)
Rockville, MD 20850

Subject: Frederick Imaging Center - MAP ID# 15568/FDA ID# 231860,

Dear Sharon:

Enclosed are the following requested documents:

- 1. Entry Application for a "new" facility (7/22/04) ACR staff noted that the facility was at the same address as a previously accredited facility with the same unit in technologist. ACR advised the facility that they would need to reinstate under the old 1 L P ID#.
- 2. Reinstatement Application with corrective action for failed test.
- 3. Although we have no documentation showing that Dr. Korangy purch is d this facility from another owner, I've enclosed documentation showing Dr. Korangy as the current owner (see Survey Agreement in 1) and closure documentation from the previous owner.

Please let me know if you have any further questions.

Sincerely.

Priscilla F. Butler, M.S., FAAPM, FACR

ings F. R. de

Senior Director, Breast Imaging Accreditation Programs

Enclosure

cc: Pamela Platt

Marion Boston

Diane Zawacki

Vickie Jernigan

Charles A. Finder, M.D.

Michael P. Divine

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MAPIDNA _ 15568

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Code of Virginia 8.01-581.17

American College of Radiology 1891 Preston White Drive, Reston, VA 20191-4397	Mammography Actre litation Program Entry Application ~ Page 1
THE DERILES IN CHARGE THE PROPERTY OF BOTH YOUR ACRE AND A CONTROL OF THE PROPERTY OF BOTH ACRE AND A CONTROL OF THE PROPERTY	there and on all correspondence)

1,	Facility name: (maximum of 60 characters; this name will expeal on both your ACR and MOSA cartification and on all correspondence) [FREDERICK IMAGINE CENTRES	
	Straet address: 46B Thomas Johnson Drive. (physical location of facility) Swite 100	
	otyllown; Frederick, StateProvince: MD	ZP: 21703
	Mailing address (If different from above):	
	Street address:	
	City/Town: State/Province:	ZP:
	Telephone (appointments): 1301 696-1410 Ext. Feet (301) 69	a- 1408
	Feeliky owner: Amile Koranay MD BIN (8 digites): 5 2-13(2	
	Facility president or CEO: Koraugy Amile	
	Contact person: Fuller Mona R	R-T (PVW)
	Lies First N	Dagrae
	Contact telephone: (301) 696-1410 Ex. E-mell address:	
2	Mammography accrediting body (AB) previously used: [MA, this facility has never applied for before,	
	ACR MAP ID No MOSA Expiration Di	3 :
	State AB State ID No. MOSA ID No. MOSA Expiration Dr	B: 1
3.	Does your radiology group have other marninography facilities accredited by the ACR? checkone 🔲 1 No 🔀 2 Yea, specify sell-	ė į
	Facility Name MAP ID No. Facility Name	MAP ID No
	Reltmare logging Ctr. Maidenshoise 106468-03 Reltimare logging Ctr York 15406-01	-
	Baltimore Imaging Ctr Old Court 10878-01	
4.	is this facility accredited by the ACR for other imaging modelities? shack one	
	Stereolocijo Breant Blopny SBBAP ID No Magnetic Resonance Imaging MRAP ID No Computed Tothic (in	y CTAPIDNo.
	Breast Ultrasound BUAP ID No Nuclear Medicins NMAP ID No Rediography/friu no	NE OPP REAP ID No.
	Ultrascund UAP ID No. Supervising radiologist (lead interpreting physician): Has the supervising radiologist previously been an interpreting physician at an accredited facility? COCHES - 02	
5.	Supervising radiologist (lead interpreting physician): D. Amile Karaugu	
6.	Has the supervising radiologist previously been an interpreting physician at an accordited facility?	
	X Yes, socialization was granted to MAP ID No. all of the above narmed socilities 700 -01	
	No, applied but accordination has not yet been granted to MAP to No, No, first application	n · f bie physicien,
7.	Does this facility accept self-referred patients?	
8.	Indicate the number of menunograms performed in the prior 12 months: Total 6	1.
	#Screening #Undifferentiated If open fact than 12 mor. is	s, imonifie open 3005.
	In order to apply, you, must meet all the requirements specified in FDA's Guality Mammagraphy Standards; Final Rules (April 28, 1999, (See Instruction Sheet for questions 9-12)	h went into effect
<i>9</i> .	Dose each interpreting physician meet the FDA personnel requirements?] 2 Yes
. 10.	. Does each radjulogic technologist meet the FDA personnel requirements?	[] ² Yes
11.	Does each medical physicial meet the FDA personnel requirements?	[] ² Yes
	Do you have a QC program (equipment) and QA program (medical outcomes sadis) that complies with the FDA rules?	[] 2 Yes
		6 A

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American College of Radio 1891 Presion White Drive, Rest	on, VA 20191-4397	Mammography A Entry		litation Program	
Feelly name: Forderick Imagin	a Centers				
How many mammography units are there at this location? enter	a number	Make copies of p	ag i 21	additional memmography units.	
D _e	scribe the mammagraphy unities	of this site.			
Unit Room #:		Unit来		1	
Mamufacturer (see code table below): S I E C	if manufacturer code is not eval	able, specify menufacturer:			
Mammana Unit Striet Number	mber (check with service engineer if un:	un): 10013	(88	Manufactured: 200	
Type of recording system(s) used with this unit: X Screen-film	n Full-field digital mammography u	nit Computed radiography (CR)	ine jin	xorex delt	
Does this unit must equipment requirements described in FDA's	a Quality Mammography Standards; i	Ind Rules (effective 4/28/99)?		Na 2Yea	
Date that the unit's most recent medical physicist survey or a n	ow unit's Equipment Evaluation was	completed: (all liens must pass)	<u>C</u> 7	123 12004 day year	
NEW UNITS ONLY: Submit the results of your medical papplication) before using this new unit to examine patients. MGSA Requirements for Mammagraphy Equipment checklist	All deficient limms must be corrected	To expense its the musice stour a	melle al 1	walcat must complate the	
Does this unit move from the primary site to other sites (mobile)? Is this a new unit that has not undergons accreditation at this location? Here this new unit moved here from a sister site?					
Her this new unit moved here from a sister site?	No.	2 Year MAP ID#	/		
Did this new unit replace an older one? (if yes, please complete		2 Yes			
Manufacturer.	Madel:	Sorial R:		Year:	
MAP Unit #: Date Re	mayed From Service:				
Signature:	Pz	int Neme:			
	Memmography Unit Manufacture	r Codes			
BEXR - Bennett GEMS - General Bectric GEND - Gendex-Del GEND - Gendex-Del GENX - General X-Ray IMSC - TMS	INRU - Instrumentarium LRAD - Lorad MOTI - Moti PHMS - Philips	PICO - Picker PLAN - Planmed SIEO - Siemens SORX - Boredek		Trex Medical Other (and specify)	
After completing the form, consult the enclosed remittence productivest, celculate your fee, and complete the following. Payment must accompany the ax rite. Ion. The application fee is 5 1325 Charge credit card Card No. 5490-9950-7025-1472Exp. Deta 03/05 VISA Mee nC d American Express Name of Cardholder: AMILE B. KORANCY Signsture: M-Korang L					
Mail your completed application to: MAMMOGRAPHY ACCREDITATION PROGRAM AMERICAN COLLEGE OF RADIOLOGY 1801 EXECTION MALTIE DRAFE	For cred	Rcard applications, <u>FAX</u> to: (703) 548-9176	M_{2}	W) 15568	

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This Mammography Accreditation Survey Agreement must be signed by the facility's superv sin radiologist (lead interpreting physician) and the Facility President/CEO or other legally constituted representative of the facility Signatures may be original or faced. Stamps, electronic, or photocopied signatures are unacceptable. The Food and Drug Administration requires accreditation of facilities providing mammography services prior to full certification.

agr.

American College of Radiology Mammography Accreditation Program 1891 Preston White Drive Reaton, VA 20191

MAMMOGRAPHY ACCREDITATION SURVEY AGREEM ENT

The undersigned hereby request a survey of the quality of mammography service being perf m ed at the location listed below. The purpose of this request is to apply for mammography accreditation at the lister location.

Facility Name and Address:	Frederick	Imagina	Centers	
	46B Tho	hob zone	inson Dri	· e
_	Suite 10	0		
	Frederick	Mary	land is	102
The American College of Ra			Ĭ	

The American College of Radiology will render an objective review in regard to the finding and in regard to whether or not the mammography equipment should be accredited by the American College (fl adiology.

As a condition of receiving the requested survey the Supervising Radiologist (Lead Interp eting Physician) and Facility Representative agree to:

- 1. Submit with the survey application the non-refundable fee for an accreditation survey. which is based upon the number of individual mammography units to be reviewed.
- 2. Obtain the designated mammographic detail phantom meeting the criteria specified by the ACR Committee on Mammography Accreditation and, if appropriate, remit the fee for the jobs atom directly to the manufacturer.
- 3. Provide, in a timely manner, all materials, including clinical images, phantom images, desimeter and QC data or any other information necessary to evaluate the mammography services for ac re litation purposes.
- 4. Receive the written final report and any peer review information by the supervising radia logist (lead interpreting physician).
- 5. Ensure that quality assurance and all other accreditation criteria are met and continue of a complied with during the accreditation period.
- 6. Perform review of mammography practice on-site by the off-site supervising radiolog st lead interpreting physician) at least quarterly, consistent with the "Off-Site Radiologist" paragraph in the ocument entitled Mammography Accreditation Program Overview.
- 7. Submit requested personnel, equipment and QC data to the ACR during the annual up lat :
- 8. Upon timely notice, and if requested by the ACR, submit to a pre-accreditation and/or protected training on-site visit conducted by a survey team designated by the ACR. In connection with the in-site survey, provide all documentation, including but not limited to QC logs, images, records, or any necessary information requested by the survey team and cooperate with the survey team.
- 9. Provide immediate written notice of a change in the supervising radiologist (lead inter notice of a change in the supervising radiologist (lead inter not ing physician) or the mammography unit to the ACR.

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- 10. Provide immediate written notice to the ACR upon the initiation of any action to charge FDA-approved accrediting bodies.
- 11. Provide immediate written notice to the ACR upon the termination of mammography ar vices provided by the facility.
- 12. Remove from public display all ACR Accreditation Certificates, Certification Marks un Decals provided to the facility as a result of this survey agreement upon termination of mammography se vices provided by the facility or upon request by the ACR.
- 13. Ensure patient notification and access to medical records if the facility ceases operations as the result of bankruptcy, dissolution, insolvency or other actions affecting the facility's ability to tun tion.
- 14. The ACR retains the right to issue a written report upon written request to any of the signatories of this agreement, but only so long as the requestor is serving in the official capacity as outline in this agreement.

The undersigned, in an individual and agency capacity, hereby release and forever discharge the American College of Radiology, its directors, officers, members, agents, volunteers, and employees it or and against any and all claims, suits, damages, losses, expenses (including attorneys' fees), and liabilities by less on of, arising out of, or related to participation in the aforesaid survey of the practice of mammography at the lists i location and the making of any report, statement, or recommendation, or failure to make a report, statement or recommendation, or the loss, damage or destruction of any image, record or other items received from the facility in ith respect to the aforesaid practice of mammography, including but not limited to any such claims or other matters based on alleged or actual negligence, antitrust, misconduct, defamation, personal injury or economic loss, catastrophic event (flood, fire, wind or other event), failure to attain accreditation or any actions that may be aken by others as a result of the survey when such actions performed by or on behalf of the ACR are done in groc faith and without malice in connection with conducting this survey.

The undersigned also agrees that the ACR is a health care entity as defined by the Heilth Care Quality Improvement Act of 1986 (HCQIA), and thus is afforded all the protections due such entities and all documentation collected as part of the accreditation process be considered poer review, privileged and confidential communications.

The above obligations are agreed to and understood. Failure to abide by any of these conditie is could result in denial, suspension or revocation of accreditation. These obligations will survive the gr nt or denial of accreditation by the American College of Radiology.

Executed on 7/22/04	Signature of Supervising Radiologist/Lead Interprating Physician
/ Date	Signatule of Supervising Radiologist/Lead Interp: sting Physician
	AMILEA. KERNOY
	Print Name of Supervising Radiologist/Lead Intag reting Physician
Executed on 7/22/04	Signature of Facility Fresident/C Et
Date	Signature of Facility President C Et
	AMILE A. KORANGS
	Print Name of Facility President/ E)
Por ACR Office Use Only:	() . A . 17
Executed on July 5, 2004	Samula alliters.
Date	Assistant Executive Director

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46 B Thomas Johnson Drive Lower Level Lobby Entrance Frederick, MD 21702 301/846-9909 • phone 301/846-0709 • fax



Mammography Accreditation Program American College of Radiology 1891 Preston White Drive Reston, VA 20191-4397

May 10, 2004

Regarding: Closing of facility ID number 231860

To Whom It May Concern:

This letter is to inform you that Frederick Radiology & PET Center, LLC has ce used operations. (Facility ID 231860, MAP ID 15568-01). The Siemens Mammo: na: 3000 NOVA 2003 is currently on site, but has been internally disconnected by the manufacturer. Frederick Radiology & PET Center vacated 46B Thomas John sc 1 Dr., Lower Level, Frederick, MD 21702 by April 30, 2004.

We are in the process of contacting all patients by letter to inform them of detail; regarding how to obtain their medical records. Please be assured, we are makin; every effort to contact each patient, and to do whatever is necessary to place the ma ni lograms in the hands of the patients.

Please feel free to contact me if there are any questions or further instructions as to our obligations. I can be reached at my home office, 301.855.3768 or cell, 301.980 5393.

Sincerely,

Laura A. Reidv

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Mammography Accreditation Program

American College of Padiology

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Reston, VA 20191-4397

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FACILITY CLOSURE MEMORANDUM

DATE	5/18/04	PRIVILEGED and CORP.	Dential = Berreview Code 0 Vu pře 8.81-81.17
TOi	Dr. Luther Wells Frederick Redictory and PET Center 46 B Thomas Johnson Drive Prederick, MD 21702	MAP;18588 (921)	15568
FROM:	Priscills F. Butler, MS Senior Director, Breast Imaging Accre	editation Programs	1
SUBJECT:	Manmography Facility Cloams – Van	ification Request	
facility may necessary the manuscraph business day president (E) below. You manuscraph intending in a possible (but you, this monthly in the	o College of Radiology Manunography of longer be performing manunography, a please check the appropriate box, signed by a Rease fix the lotter to Ms. Pamela just also remove the light blue ACR Man recility. Also note that the FDA require a films and reports as described in their sections within the next future), please eswithin 10 business days) to notify us of no will serve as written confirmation by Accreditation Program and we will not	If your facility has permanent helow and return this letter of the facility's super Plate at (703) 648-9176 or amnography Acareditation cees that you amange for the intesched Guidance on Recordity (or has temporarily ceased it Ms. Plate at (800) 227-64 fyour facility's intentions. It that your facility has with	may con led performing to the LC: within 10 wising an elogist or sond it to be address crificates) can public master of each patient's Koopin; I mamming play and is 40, x-41 95 is soon as few do no hear from drawn for the ACP
Finally, pleas inspection.	e note that as long as your facility :	is MQSA-cartified, it is so	bjeot u FIA/MQSA
Mack Resource	hy has permanently coated performing I by M. D. Provide name Agnature Statist moved to sizer size Chankrupacy of to Please provide the name and phone must on retrieving their original manamographs	Supervising Radiologist (circle S/18/date s date s formula! Oxforming problems ander of a person that your pe	Excilin Pri ident/CEO a che) out igned

Facility accredited in and also permanently coming: Istoreotante Break Bropey (I Break Ut second